

### **REMARKS/ARGUMENTS**

The Office Action dated February 13, 2007, rejected all pending claims (i.e., claim 1-7) for allegedly being indefinite, anticipated, and/or obvious, objected to the use of trademarks in the specification, and provisionally rejected the pending claims for double patenting.

In light of these rejections and objections, Applicants have amended the claims and specification in an attempt to advance prosecution. It is believed that the currently pending claims are in condition for allowance, and an indication of allowability is earnestly solicited.

Applicants thank the Examiner for acknowledging the election as set forth in the Reply dated December 15, 2006.

#### **Amendments to the Specification**

Applicants have amended the specification to capitalize the trademarks CARBOPOL and KLUCEL. Applicants do not believe that povidone is a registered trademark. Accordingly, it has not been capitalized. Because the generic terminology for CARBOPOL and KLUCEL already accompanied these trademarks, Applicants have not added any such language to the specification.

#### **Claim Objections**

The Patent Office objected to claim 4 due to a misspelling. Because claim 4 recites the elected species and does not further define the subject matter in claim 1,

Applicants have canceled claim 4. Applicants accordingly believe that the objection is moot.

### **Indefiniteness Rejection**

The Patent Office rejected claims 3-4 and 7 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. In one part, the Office alleged that the terms “by weight percentage,” “10 to 20 an adhesive polymer,” and “10 to 20 polyvinylpyrrolidone” are unclear, and requested clarification. In another part, the Office has noted that Claim 3 contains trademark terms (carbopol 974P and povidone K-90) and thus describes a particular material or product, which, in combination with a larger range, results in a claim that does not clearly set forth the metes and bounds of the patent.

In an effort to advance prosecution, Applicants have amended claim 3 to address these rejection. Applicants have amended the claims to remove an explicit recitation of the tradenames for preferable materials. The as-amended claim is well supported in the specification (for example, page 3, paragraph before last and ending on page 4, 2nd paragraph, in the section beginning from page 4, last paragraph and ending on page 5, 3rd paragraph, and also in the section beginning from page 8, last paragraph and ending at the end of page 9). Applicants respectfully submit that the as-amended claim addresses the outstanding indefiniteness rejection this amendment, thus placing independent claim 3 and dependent claim 7 in condition for allowance.

### **Anticipation Rejection**

The Patent Office rejected claims 1-4 under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent App. Pub. 2003/0003140 A1 to Domb et al. (“Domb”).

In particular, the Office alleges that Domb teaches a composition of a topic self-adhesive sticker for treating mucosal diseases, comprising *Echinacea purpurea*, Elder (*Sambucus nigra*), Gotu-kola (*Centella asiatica*) (Table 1), povidone (polyvinylpyrrolidone) (paragraph 0147), acrylic acid polymers (claim 23) and tableting excipients (claim 24). At least some of this information appearing in Domb does not belong to Mr. Domb; rather, it belongs to the assignee of the present invention. In fact, legal action has been taken against Mr. Domb over the information appearing in Domb.

In accordance with MPEP § 716.10, Applicants submit a declaration under Rule 132 to show that the information disclosed in Domb was derived from Applicants. Accordingly, the Patent Office’s rejection should be removed. The declaration explains the relevant facts:

- Avraham J. Domb was a paid consultant for Herbal Synthesis Corp. (“Herbal Synthesis”).
- Herbal Synthesis Corp. became Izun Pharmaceuticals Corp. on January 21, 2005 (“Izun”).
- Mr. Domb signed and executed a confidentiality agreement concerning the scope of his work for Herbal Synthesis. This confidentiality agreement is attached to the declaration as Exhibit A.

- The data that belongs to Herbal Synthesis/Izun appears in the Domb publication as Table 1, in Example 2 (pages 8-10), which, *inter alia*, discloses combinations of *Echinacea purpurea*, Elder (*Sambucus nigra*), Gotu-kola (*Centella asiatica*) and povidone (polyvinylpyrrolidone). A contemporaneously generated report reviewing the source of the data appearing in the Domb publication is attached to the declaration as Exhibit B.
- Applicants conceived and invented subject matter appearing in the published application as noted above.

Applicants understand that the assignee of the present invention, Izun, is in possession of a declaration by Mr. Domb, which was obtained during previous legal proceedings, which confirms the above course of events and facts. Applicants have alerted their lawyers of the possible need for this document. The undersigned understands that this document will only be released if the United States Patent & Trademark Office deems it necessary to establish inventorship by the Applicants of the above-identified information appearing in Domb.

Because Domb is not prior art under 35 U.S.C. § 102(e), Applicants respectfully request withdrawal of the anticipation rejection.

### **Obviousness Rejection**

The Patent Office rejected claims 1-7 under 35 U.S.C. § 103 as allegedly rendered obvious by Domb in view of U.S. Patent No. 5,543,154 to Rork et al. ("Rork") and U.S. Patent No. 5,780,046 to Humber et al. ("Humber"). The Patent Office also rejected claim

1 as allegedly rendered obvious by PCT Publication WO 02/094300 A1 to Levine et al. (Levine '300) in light of Domb.

As noted previously, Domb is not prior art. Accordingly, these rejections should be withdrawn. Nevertheless, Applicants note that while both Rork and Humber may mention specific compounds, they do not imply nor suggest the particular combination as defined in the presently pending claims. Without Domb, these publications do not render obvious the presently claimed subject matter. Furthermore, Levine '300 does not teach a composition of a topic self-adhesive sticker for treating mucosal disorders, but rather teaches a composition of extracts. Thus, Levine '300 does not render obvious the presently claimed subject matter.

#### **Provisional Double Patenting Rejection**

The Patent Office has provisionally rejected claim 1 for nonstatutory obviousness-type double patenting over claims 1, 20, 24, 25, 35, 39, 40, 50, 62, 68 of co-pending App. No. 10/478,718 (which claims priority to Levine '300).

Because a double patenting rejection is only proper over an issued patent, Applicants request that this rejection be held abeyance until the Patent Office either this application or the '718 application matures into a patent. At that time, the Office and Applicants may re-evaluate whether the allowable and issued claims are obvious over each another.

Applicants note, though, that the '718 application's claims do not teach or suggest a composition of a topic self-adhesive sticker for treating mucosal disorders; rather, that

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application's claims relate to a composition of extracts. Accordingly, the nonstatutory provisional double patenting rejection should be withdrawn.

Respectfully submitted,

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